

REMARKS

Application Status

In the January 21, 2005 Office Action, the Examiner rejected claims 1, 2, 15, and 25 under 35 U.S.C. § 101 as "non-statutory subject manner . . . including . . . a human being or portions thereof."

Claims 3-5, 13, and 16-18 were rejected under 35 U.S.C. § 102(b) as anticipated by Crozet (WO 98/48738). Claims 3-8, 13-14, 16, 18, 23, 24, and 26 were rejected under § 102(e) as anticipated by Boyd et al (U.S. Pat. No. 6,468,311).

Claims 7-12 and 19-22 were rejected under § 103(a) as obvious over Crozet in view of Foley (U.S. Pat. No. 6,395,031).

Claims 1-26 have been cancelled and new claims 27-43 have been added.

Applicants request a one month extension and also respectfully request reconsideration and reexamination of the claims.

Rejection Under 35 U.S.C. § 101

Applicants have re-written the apparatus and method claims to reflect that the invention is an allograft which has been modified from a whole vertebral body originally harvested from a cadaver. Allograft bone structures are patentable, both in apparatus and method form. As representative examples of patents including allografts, Applicants respectfully direct the Examiner to U.S. Pat. No. 6,025,538 to Yaccarino, which is a patent for a "Compound Bone Structure Fabricated From Allograft Tissue." U.S. Patent

No. 6,156,070 to Incavo et al is directed to "Allograft Prosthetic Joints And Method."

The patent includes a natural bone allograft placed between a patient's original bone and a prosthetic implant. Other patents directed to allografts also exist.

It should be noted that the new claims identify a cross member and lateral members of the allograft. While the claims are not so limited, it is contemplated that the preferred embodiment of the invention is a single cadaveric vertebral body that is cut, modified, and sized to meet the requirements of the claims. Nevertheless, in view of the amended claims, and in view of the patentability of allografts, Applicants respectfully submit that they have overcome the Examiner's rejection under § 101.

Rejections Under 35 U.S.C. §§ 102 and 103

The apparatus and method claims as re-written are not anticipated or rendered obvious by Crozet, Boyd, and Foley, either singly or in combination.

The present invention has been designed with a configuration so that the allograft provides support to the fused vertebrae at the apophyseal ring. The apophyseal ring is well-described by Dr. Rauschnig of Sweden and others as the outer few millimeters of the anterior and lateral circumference of the human vertebral body, and that ring is capable of supporting higher loads than the softer, cancellous bone that makes up the remainder of a vertebral body. There is no apophyseal ring on the posterior aspect of a complete vertebral body. Only the portion of the vertebral body that is composed of cortical bone is strong enough to support the load of the spine on the devices placed within the disc space during anterior lumbar interbody fusion. The present invention is

designed to take advantage of its ability to provide support at the apophyseal ring to improve upon the devices commonly in use today, which typically encounter subsidence problems.

Crozet and Boyd, though vaguely similar in configuration to the present invention, are not designed to make use of the support provided by the apophyseal ring of a patient's vertebrae. For example, Crozet, on sheet 17 of 25, depicts a generally U-shaped device whose closed end is placed toward the posterior of the vertebrae, leaving the anterior portion open, so that generally cylindrical devices can be threaded into the U-shaped portion to form a single modular device. Like Crozet, Boyd also relies on a larger supporting surface area of soft, cancellous bone, which may be helpful, but which may still be subject to subsidence. Crozet and Boyd are two more modular devices similar to others that have clinically failed with appreciable frequency. Many of those failures are attributable to either subsidence of the modular device, its complexity, or both.

In contrast to Crozet, the allograft in the present invention is open at the posterior aspect of the vertebrae, where there is no cortical bone for support. The closed end of the allograft fits in the anterior aspect of the vertebrae and takes advantage of virtually all of the apophyseal rings of the allograft and the vertebrae between which it is interposed. Another advantage of the present invention is that it does not require a compatible modular system, such as the one depicted in Crozet. The present invention can be adapted for use with a variety of support devices placed posterior of the allograft.

Boyd does not anticipate the present invention nor render it obvious for the same reasons as Crozet. Figure 4 of Boyd, when compared with Applicants' invention, clearly

does not contemplate the use of the apophyseal ring of adjacent vertebrae, nor does Boyd even appear to have the structural equivalent of an apophyseal ring. That Boyd contemplates his implant may include portions made of bone does not render the present invention unpatentable. As described in the Abstract of Boyd, the use of bone is only "to promote fusion of the vertebrae." Boyd contemplates "the use of bone segments otherwise unsuitable due to size or strength." While the bone allograft of the present invention will promote fusion of the vertebrae, it is also patentably distinct from Boyd because Applicants' device does contemplate bone of suitable strength that is cut and sized for its specific application and to obtain the strength advantages of the apophyseal ring.

The combination of Foley with either Crozet or Boyd does not render the present invention obvious. Foley is simply a spacer that is unlike the present invention in either structure or function.

Conclusion

Applicants respectfully request reconsideration and reexamination of the claims. In view of the amendments and the preceding remarks, a prompt notice of allowance is

Earnestly solicited. If the Examiner has any comments or questions regarding this amendment, please telephone the undersigned.

Respectfully submitted,

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